Introduction to CE marking

Course Description

Attend BSI's "Introduction to CE Marking" one day course and start making informed decisions with regards to meeting the requirements of the EU Medical Devices Directives. On completion of the training, participants will be able to identify the steps required to reduce the risks and uncertainty in the EU regulatory process and thus bring products to the EU market more quickly.

Learning Objectives

On completion of this training, participants will be able to:

- Explain the European CE marking approach with respect to medical devices, active implantables and IVDs, including borderlines with other products, as covered by the three Council Directives (MDD, AIMDD, IVDD) and the underlying Commission Directives such as the animal tissue directive and blood derivative directives
- Prepare a clinical evaluation in accordance with MED DEV 2.7.1 and GHTF Guidance Documents
- Explain the significance of the EU risk classification criteria for medical devices in determining the conformity assessment routes and quality assurance requirements for the various risk classes, as well as the routes to compliance for borderline products that include pharmaceuticals, human derivatives and/or engineered tissues
- Describe the role of the essential requirements as the basis for CE marking, including the use of standards
- Describe the role of clinical data and risk management
- Identify the necessary steps required for post market surveillance and for reporting adverse incidents under the vigilance system
- Identify technical documentation requirements.

Intended Audience

- Senior management
- Regulatory, quality, design, development, manufacturing, marketing managers and personnel
- Organizations preparing 'own branding' or 'private labelling' of devices.

Course Duration

One day.

Prerequisites

There is no prerequisite for this course but participants will benefit from a basic knowledge of medical device use or manufacture.

How will I learn?

We use accelerated learning techniques that encourage interaction and collaboration, keep the course varied and put your learning in context. Our tutors are the best in their field and will make sure your learning needs are met. Choose between public or in-company courses tailored to your business – whatever delivers the most positive and successful outcome for you.

Where will I learn?

We deliver five star learning at first class venues. Each venue has been selected to provide the best possible learning environment so you can maximize your learning experience.

Who are we?

As an EU Notified Body, our expertise is in auditing to the requirements of the Directives. Our tutors are skilled in transferring knowledge contained within each standard to help you embed excellence within your organization. With over 65,000 clients in 150 countries worldwide, you can trust BSI to help you perform better, reduce risk and grow sustainably.

Why train with us?

We've trained and audited thousands of businesses using the same standards so we can genuinely benchmark performance. And we can take you from beginner to certification quickly then support you with follow-up courses and webinars – and all this for the price of your course.

Did you know?

Our tutors are active practitioners in their subjects, ensuring the latest developments are fully understood. We are the leaders in medical devices regulatory expertise with over 200 BSI Medical Device product and regulation experts around the world.

Next step:

To book this course, call one of our dedicated training experts on +44 845 086 9000 or book online at bsigroup.co.uk/training

In-company Training

Discuss your product development in confidential surroundings by opting for bespoke in-company training.